

In the Claims:

D2

1. (Amended three times) An *in vivo* method of treating a mammalian host capable of generating an immune response, which comprises:

- (a) generating a DNA fragment which expresses an antigenic protein or antigenic protein fragment;
- (b) distributing said DNA fragment on a particle surface, resulting in a particulate polynucleotide;
- (c) inoculating said mammalian host with said particulate polynucleotide; and,
- (d) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell within said mammalian host, such that said expressed antigenic protein or antigenic protein fragment is presented to the membrane surface of said antigen presenting cell through the MHC class I pathway, wherein said presentation of said antigenic protein or protein fragment elicits [an anti-tumor or anti-viral] a primary CTL immune response in said host that destroys neoplastic or virally infected cells.

D3

15. (Amended three times) An *in vivo* method of treating a mammalian host capable of generating an immune response, which comprises:

- (a) generating a DNA fragment which expresses an antigenic protein or antigenic protein fragment;
- (b) distributing said DNA fragment on a particle surface, resulting in a particulate polynucleotide;
- (c) inoculating said mammalian host with said particulate polynucleotide using a biostatic device; and,
- (d) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell within said mammalian host, such that said expressed antigenic protein or antigenic protein fragment is presented to the membrane surface of said antigen presenting cell through the MHC class I pathway, wherein said presentation of said antigenic protein or protein fragment elicits [an anti-tumor or anti-viral] a primary CTL immune response in said host that destroys neoplastic or virally infected cells.

D4

29. (Amended three times) An *in vivo* method of treating a mammalian host capable of generating an immune response, which comprises:

- (a) generating a DNA fragment which expresses an antigenic protein or antigenic protein fragment;
- (b) distributing said DNA fragment on a particle surface, resulting in a particulate polynucleotide;
- (c) inoculating said mammalian host with said particulate polynucleotide by direct injection; and,

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(d) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell within said mammalian host, such that said expressed antigenic protein or antigenic protein fragment is presented to the membrane surface of said antigen presenting cell through the MHC class I pathway, wherein said presentation of said antigenic protein or protein fragment elicits [an anti-tumor or anti-viral] a primary CTL immune response in said host that destroys neoplastic or virally infected cells.

44. (Amended three times) An *ex vivo* method of treating a mammalian host capable of generating an immune response, which comprises:

(a) generating a DNA fragment which expresses an antigenic protein or antigenic protein fragment;

(b) distributing said DNA fragment on a particle surface, resulting in a particulate polynucleotide;

(c) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell of a mammalian host *in vitro*, such that said expressed antigenic protein or antigenic protein fragment is presented on the membrane surface of said antigen presenting cell through the MHC class I pathway; and,

(d) inoculating said mammalian host with said antigen presenting cell by direct injection, wherein presentation of said expressed antigenic protein or protein fragment on said antigen presenting cells of said hosts elicits [an anti-tumor or anti-viral] a primary CTL immune response that destroys neoplastic or virally-infected cells in said host.

REMARKS

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-3, 5-17, 19-32, 34-47, 49-61 and 63-71 were rejected under 35 U.S.C. §112, first paragraph, for allegedly not being enabling for the breadth of the claims. This rejection is respectfully traversed.

The Office Action asserts that the invention covers any anti-tumor or anti-viral response and as such the claims should be amended to reflect the particular MHC Class I effect. Applicants' claims have been amended to recite that the response elicited by the methods of this invention is a primary CTL response.

In addition, the Office Action indicates that the evidence submitted by the Applicants only enables biolistic injection into the skin. Applicants respectfully submit that both the biolistic gene-gun method and the direct injection method of administration are enabled by the specification. Example Sections 7 and 8 (and corresponding Figures) clearly show that biolistic immunization is an effective means for accomplishing the present methods and that subcutaneous injection of particulate polynucleotides is as effective as the biolistic approach in eliciting a CTL immune